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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,936	11/07/2001	Olle Korsgren	KORSGREN-1	9165

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EXAMINER	
JAGOE, DONNA A	
ART UNIT	PAPER NUMBER
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.	Applicant(s)	
	09/890,936	KORSGREN ET AL.	
	Examiner	Art Unit	
	Donna Jagoe	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4,8,9,11 and 14-26* is/are pending in the application.

4a) Of the above claim(s) *14-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4,8,9 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The amendment filed June 21, 2006 has been received and entered. Claims 4, 8, 9 and 11 are pending in this application.

Newly submitted claim 26 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claim 26 is drawn to a method of using the isolated islets wherein the islets are injected into the bloodstream of a patient suffering from insulin dependent diabetes mellitus. This is separate and distinct from the method of using the islets generally.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 26 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Response to Arguments

Applicants' arguments, filed June 21, 2006, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 4 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Wagner et al. DE 196 23 440 A 1.

Wagner et al. teach method of use of anticoagulants such as heparin, hirudin and Marcumar and derivatives thereof in connection with transplantation of

insulin producing cells such as islets of Langerhans (see claim 8). The cells may be in the form of microencapsulated islets (see figure 1 and claim 10) and where immunosuppression can be an issue, see "Islet Transplant Info" that teaches that immunosuppression and/or appropriate drugs, such as Zenapax should be used to address the issue. The abstract for Wagner et al. teach that the immobilized material is insulin, proinsulin and/or organ cells of xenogenic or autogenic origin (islets of Langerhans, etc.) and the system contains an agent to inhibit or suppress blood agglutination, agglomeration antagonists, heparin, hirudin, marcumar and their derivatives. Wagner discloses that the islets *may* be microencapsulated. Additionally, if the cells are microencapsulated, they are first mixed with the anticoagulant material, thus anticipated the claims of the instant application.

Claims 4 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Soon-Shiong et al. U.S. 5,705,270 A.

Soon-Shiong et al. teach microcapsules containing biological material such as islet of Langerhans cells coated with polymerizable materials (see abstract, see also claim 3). The microcapsules are covalently linked with heparin (see claim 5). Soon-Shiong et al. teach encapsulation of islets of Langerhans for treatment of diabetes (column 4, lines 1-4) to prevent the detrimental effects of capsule instability on the encapsulated biologically active material e.g. loss of immunoprotection for the encapsulated material is minimized (column 3, lines 61-66). Additionally, note that there is no provision in the instant claims that deals with the immunosuppression issue, without which, the transplanted islet cells would be rejected (see Islet Transplant Info).

The instant specification describes immobilizing heparin according to a method developed by Corline Systems AB disclosed in WO 93/05793 (page 4 of the instant specification). The heparin in WO 93/05793 appears to be immobilized (conjugated) with a polymer comprising a substantially straight-chained organic homo or hetero polymer having a number of functional groups distributed along the polymer backbone chain via which groups at least about 20 molecules (see page 7 of WO 93/05793). While applicant asserts that the heparin is not in microcapsules, it appears that it is similarly coated and as such, must form micro (or macro) capsules if applicant has followed the technique of Corline Systems AB as recited in applicants specification.

Claims 4, 8, 9 and 11 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Bennet et al. (Incompatibility Between Human Blood and Isolated Islets of Langerhans: A Finding With Implications for Clinical Intraportal Islet Transplantation, Diabetes, 1999 Vol. 48 pages 1907-1914).

Bennet et al. teach transplantation of isolated islets of Langerhans with heparin and optionally the complement inhibitor sCR-1 (page 1908, col. 2, 3rd full paragraph). Bennet et al. teach the disruption of the integrity of the islets could be prevented by the addition of heparin in combination with the complement inhibitor, soluble complement receptor 1 (sCR-1) (page 1908, column 1, 2nd full paragraph to the 3rd full paragraph). Bennet et al. state that "most centers performing allogenic islet transplantation today use systemic heparin at the time of transplantation. Heparin is usually administered as a bolus dose. Addition of heparin prevented coagulation, reduced cell consumption and to a large degree, inhibited complement activation, but the addition of heparin in

combination with sCR-1 effectively inhibited coagulation and complement activation (page 1913, 1st full paragraph).

Applicant asserts that Wagner discloses and seemingly denigrates a prior micro capsulation system where the islets are enclosed in capsules made of alginate complexed with polylysine. While applicant asserts that the heparin recited instantly is not in microcapsules, it appears that it is similarly coated, and as such, must form micro (or macro) capsules if applicant has followed the technique of Corline Systems AB as recited in applicants' specification on pages 4-5. WO/93/05793 described in the instant specification as modifying the heparin surface is a polymer, and specifically recites the polylysine as a carrier polymer for the heparin. Applicant asserts that the Corline Systems is in reference to a device, the tubing. However, the examiner is not in agreement. The Corline System is drawn to "modified heparin". During patent examination, the pending claims must be "given their broadest reasonable interpretation consistent with the specification". Further, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., surface modification of each islet without changing the physical configuration of the islet) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Further, the claim language comprising does not exclude the islet transplantation method of Wagner.

Applicant's arguments regarding Soon-Shiong et al. have been fully considered but they are not persuasive. Again applicant asserts that the instant claims do not employ a chemically modified heparin, but the specification states that it does in the method of chemically modifying the surface of the heparin in the method of Corline Systems AB wherein the heparin is bound to a polymer carrier. Further, the claim language comprising does not exclude the islet transplantation method of Soon-Shiong et al. Applicant asserts that the Corline Systems does not use a heparin alginate conjugate. The Corline system employs chitosan and both alginate and chitosan are natural polymers and both fit the description of claim 1 of Corline Systems, a substantially straight-chained organic polymer having a number of functional groups distributed along the polymer backbone chain. Thus the modified heparin, being modeled after the Corline System's surface modified heparin, does not exclude the heparin alginate conjugate with islet cells as in Soon-Shiong et al.

Regarding Bennet, applicant should submit an argument under the heading "Remarks" pointing out disagreements with the examiner's contentions. Applicant must also discuss the references applied against the claims, explaining how the claims avoid the references or distinguish from them.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Thursday from 9:00 A.M. - 3:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Donna Jagoe
Patent Examiner
Art Unit 1614

December 29, 2006

12/31/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER